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June 04, 2014

The Honorable Board of Supervisors
County of Los Angeles
383 Kenneth Hahn Hall of Administration
500 West Temple Street
Los Angeles, California 90012

Dear Supervisors:

**APPROVAL OF AMENDMENT TO AGREEMENT WITH LOS ANGELES
BIOMEDICAL RESEARCH INSTITUTE
(SUPERVISORIAL DISTRICT 2)
(3 VOTES)**

SUBJECT

Request approval of an Amendment to extend the Agreement with Los Angeles BioMedical Research Institute for one year and delegation of authority to extend the Agreement term further for up to an additional 12 months, for the continued provision of Medical Research and Education Services at Harbor-UCLA Medical Center.

IT IS RECOMMENDED THAT THE BOARD:

1. Authorize the Director of Health Services (Director), or his designee, to execute Amendment to Agreement No. H-201979 with Los Angeles BioMedical Research Institute (LA BioMed), effective upon execution, to extend the term of the Agreement for the period of July 1, 2014 through June 30, 2015, with the option by the Director to further extend the Agreement term for up to an additional 12 month period, for the continued provision of medical research and education services, at no cost to the County, at Harbor-UCLA Medical Center (H-UCLA MC) and to update Agreement provisions.
2. Delegate authority to the Director, or his designee, to execute an amendment to extend the term of the Agreement for up to 12 additional months, through June 30, 2016, subject to review and approval by County Counsel, and with written notification to the Board and Chief Executive Office

(CEO).

PURPOSE/JUSTIFICATION OF RECOMMENDED ACTION

Approval of the first recommendation will allow the Director, or his designee, to execute an Amendment to the Agreement with LA BioMed, substantially similar to Exhibit I, to extend the term of the Agreement for one year to June 30, 2015 to continue the administration of the grant-funded research and education projects on the H-UCLA MC campus. The current Agreement expires June 30, 2014. The recommended extension period is necessary to allow County time to complete negotiations of a Master Ground Lease Agreement (MGLA) that will cover 11.4 acres at the H-UCLA MC campus, encompassing five of LA BioMed's existing research buildings that LA BioMed has already constructed, as well as space for the development of two new research buildings. Upon Board approval, the terms and conditions of the MGLA will prevail and supersede specific occupancy provisions contained in this research agreement. The expectation is that there will be a replacement research agreement negotiated and executed shortly thereafter.

County (H-UCLA MC staff, CEO, and Counsel) and LA BioMed staff and their counsel conducted their latest negotiation meeting on March 12, 2014, during which all remaining issues were discussed. CEO continues to work with LABioMed on the final draft of the MGLA and anticipates making a recommendation for Board approval before the end of this calendar year.

Approval of the second recommendation will allow the Director to further extend the current Agreement up to 12 additional months to allow for continued negotiations, if necessary. Following the execution of the successor MGLA, negotiation of a new medical research and educational services agreement will begin.

Implementation of Strategic Plan Goals

The recommended actions support Goal 3, Integrated Services Delivery, of the County's Strategic Plan.

FISCAL IMPACT/FINANCING

There is no County cost or money exchanged under this Agreement for the use of County space by LA BioMed. LA BioMed provides in-kind services that both parties agree to offset the value of space support services provided by H-UCLA MC. H-UCLA MC also provides limited ancillary, therapeutic and diagnostic services LA BioMed research patients, with reimbursement paid by LA BioMed.

FACTS AND PROVISIONS/LEGAL REQUIREMENTS

LA BioMed has a long history of administering research and education projects at H-UCLA MC. The current Agreement expires June 30, 2014. LA BioMed continues to obtain grant funds and provides research and education projects that benefit the delivery of health care to County patients. Quarterly and annual reports are submitted documenting the agreed in-kind services.

This Amendment will allow LA BioMed the continued use of space at H-UCLA MC to conduct its grant-funded research and education programs, while the MGLA is completed for H-UCLA MC.

This Amendment includes recent Board of Supervisors' required provisions.

County Counsel has reviewed and approved Exhibit I as to form.

CONTRACTING PROCESS

LA BioMed has served as an integral partner with H-UCLA MC in conducting research and education projects. The County is currently in the process of updating the MGLA with LA Biomed, once that Agreement is completed and approved by the Board, a new research and education agreement will be negotiated for the continuance of these essential projects which benefit County patients.

IMPACT ON CURRENT SERVICES (OR PROJECTS)

Approval of the recommendations will allow for the continued collaboration between DHS and LA BioMed in the administration of vital research projects which benefit County patients.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Mitchell Katz". The signature is fluid and cursive, with the first name "Mitchell" written in a larger, more prominent script than the last name "Katz".

Mitchell H. Katz, M.D.

Director

MHK:ev

Enclosures

c: Chief Executive Office
County Counsel
Executive Office, Board of Supervisors

MEDICAL RESEARCH AND EDUCATION AGREEMENT

AMENDMENT No. 8

THIS AMENDMENT is entered into this _____ day
of _____, 2014,

by and between

COUNTY OF LOS ANGELES (hereafter
"County"),

and

LOS ANGELES BIOMEDICAL
RESEARCH INSTITUTE AT HARBOR-
UCLA MEDICAL CENTER, a California
Non-Profit Public Benefit Corporation
(hereafter "Institute")

Business Address:
1124 W. Carson Street No.16
Torrance, CA 90502

WHEREAS, reference is made to that certain document entitled "MEDICAL RESEARCH AND EDUCATION AGREEMENT", dated June 2, 1992, and further identified as County Agreement No. H-201979, and any amendments thereto (all hereafter "Agreement"); and

WHEREAS, it is the intent of the parties hereto to extend the term of the Agreement for a one year period, with the option to further extend the Agreement term for up to an additional 12 months, and to provide for the other changes set forth herein; and

WHEREAS, it is anticipated that the parties shall execute a Master Ground Lease Agreement (MGLA) for Harbor-UCLA Medical Center (H-UCLA MC) campus which shall include the use of space on the campus by the Institute, some of which may be included in Exhibit A of this Agreement ; and

WHEREAS, Agreement Paragraph 39, includes provisions regarding "HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996 (HIPAA) AND THE HEALTH CARE INFORMATION TECHNOLOGY FOR ECONOMIC AND CLINICAL HEALTH ACT (HITECH); and

WHEREAS, on January 25, 2013, the U.S. Department of Health and Human Services published in the Federal Register its omnibus final rule modifying the privacy, security, enforcement, and breach notification regulations under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), and made this rule effective March 26, 2013; and

WHEREAS, these revised regulations require County to modify Agreement's Business Associate Agreement provisions; and

WHEREAS, Agreement's Business Associate Agreement provisions provide that County and Contractor will take action as is necessary to amend the Business Associate Agreement in order for the County to comply with its regulatory obligations; and

WHEREAS, County and Contractor intend to amend Agreement to incorporate in Agreement the revised Business Associate Agreement provisions, which shall supersede and replace any prior Business Associate Agreement provision; and

WHEREAS, said Agreement provides that changes may be made in accordance with Paragraph 20, ALTERATION OF TERMS of the Agreement, made in the form of a written amendment which is formally approved and executed by the parties.

NOW, THEREFORE, the parties hereto agree as follows:

1. This Amendment shall commence and be effective upon execution.
2. Agreement Paragraph 1, TERM, shall be deleted in its entirety and replaced as follows:

“1. TERM:

The term of this Agreement shall commence on June 2, 1992, and shall continue in full force and effect through June 30, 2015. Either party may terminate this Agreement at any time for any reason by giving at least ninety (90) days prior written notice thereof to the other party unless the parties agree to terminate earlier pending completion of the master plan for the Hospital campus, and resulting successor agreement.

At the option of the Director of Health Services (Director), or his designee this Agreement may be extended for up to an additional twelve months, through June 30, 2016, if additional time is needed by the County to complete negotiations of the H-UCLA MC MGLA and adoption by the Board, under the same terms and conditions as specified in this Agreement following approval by County Counsel, with notification to the Board and Chief Executive Office. To implement such extension of time, an Amendment to the Agreement shall be prepared by the County and then executed by the Contractor and by the Director.

3. Paragraph 32, CONFLICT WITH GROUND LEASE AGREEMENT, shall be amended to add Sub-paragraph F as follows:

“32. CONFLICT WITH GROUND LEASE AGREEMENT AND MGLA. In the event that any terms or provisions of this Agreement conflict with or are inconsistent with any of the terms and provisions of the Ground Leases No. 1, No. 2 and No. 3, the terms and provisions of the Ground Leases shall in all cases be deemed to control. In the event that any terms or provisions of this Agreement conflict with or are inconsistent with any of the terms and provisions of the MGLA, the terms and provisions of the MGLA shall in all cases be deemed to control.”

4. Paragraph 39, HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996 (HIPAA) AND THE HEALTH CARE INFORMATION TECHNOLOGY FOR ECONOMIC AND CLINICAL HEALTH ACT (HITECH), shall be deleted in its entirety and replaced as follows:

“39. HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996 (HIPAA):

The County is subject to the Administrative Simplification requirements and prohibitions of the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191 (HIPAA), and regulations promulgated thereunder, including the Privacy, Security, Breach Notification, and Enforcement Rules at 45 Code of Federal Regulations (C.F.R.) Parts 160 and 164 (collectively, the “HIPAA Rules”). Under this Agreement, the Contractor provides services to the County and the Contractor receives,

has access to, receives, maintains, or transmits Protected Health Information as defined in Exhibit F-1 in order to provide those services. The County and the Contractor therefore agree to the terms of Exhibit F-1, Business Associate Under Health Insurance Portability and Accountability Act of 1996 (HIPAA).”

5. Agreement, Paragraph 40, TIME OFF FOR VOTING, shall be added to the Agreement as follows:

“40. TIME OFF FOR VOTING

The Contractor shall notify its employees, and shall require each subcontractor to notify and provide to its employees, information regarding the time off for voting law (Elections Code Section 14000). Not less than 10 days before every statewide election, every Contractor and subcontractors shall keep posted conspicuously at the place of work, if practicable, or elsewhere where it can be seen as employees come or go to their place of work, a notice setting forth the provisions of Section 14000.”

6. Agreement, Exhibit F, CONTRACTOR’S OBLIGATIONS AS A “BUSINESS ASSOCIATE” UNDER THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996 AND THE HEALTH CARE INFORMATION TECHNOLOGY FOR ECONOMIC AND CLINICAL HEALTH ACT (BUSINESS ASSOCIATE AGREEMENT) is deleted and replaced in its entirety by Exhibit F-1, BUSINESS ASSOCIATE AGREEMENT UNDER THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996 (“HIPAA”) attached hereto and

incorporated herein by reference. All references to Exhibit F in the Agreement shall hereafter be replaced by Exhibit F-1.

7. Except for the changes set forth hereinabove, the Agreement shall not be changed in any other respect by this Amendment, and shall remain in full force and effect.

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IN WITNESS WHEREOF, the Board of Supervisors of the County of Los Angeles has caused this Amendment to be executed by its Director of Health Services and Institute has caused this Amendment to be executed in its behalf by its duly authorized officer, the day, month, and year first above written.

COUNTY OF LOS ANGELES

By _____
Mitchel H. Katz, M.D.
Director of Health Services

LOS ANGELES BIOMEDICAL RESEARCH
INSTITUTE AT HARBOR-UCLA MEDICAL
CENTER, a California Non-Profit Public
Benefit Corporation

Contractor

By _____
Signature

Printed Name

Title _____
(AFFIX CORPORATE SEAL)

APPROVED AS TO FORM:
John F. Krattli
County Counsel

By _____
Edward Morrissey
Principal Deputy County Counsel

BUSINESS ASSOCIATE AGREEMENT UNDER THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996 ("HIPAA")

County is a Covered Entity as defined by, and subject to the requirements and prohibitions of, the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191 ("HIPAA"), and regulations promulgated thereunder, including the Privacy, Security, Breach Notification, and Enforcement Rules at 45 Code of Federal Regulations (C.F.R.) Parts 160 and 164 (collectively, the "HIPAA Rules").

Contractor performs or provides functions, activities or services to County that require Contractor in order to provide such functions, activities or services to create, access, receive, maintain, and/or transmit information that includes or that may include Protected Health Information, as defined by the HIPAA Rules. As such, Contractor is a Business Associate, as defined by the HIPAA Rules, and is therefore subject to those provisions of the HIPAA Rules that are applicable to Business Associates.

The HIPAA Rules require a written agreement ("Business Associate Agreement") between County and Contractor in order to mandate certain protections for the privacy and security of Protected Health Information, and these HIPAA Rules prohibit the disclosure to or use of Protected Health Information by Contractor if such an agreement is not in place.

This Business Associate Agreement and its provisions are intended to protect the privacy and provide for the security of Protected Health Information disclosed to or used by Contractor in compliance with the HIPAA Rules.

Therefore, the parties agree as follows:

1. DEFINITIONS

- 1.1 "Breach" has the same meaning as the term "breach" at 45 C.F.R. § 164.402.
- 1.2 "Business Associate" has the same meaning as the term "business associate" at 45 C.F.R. § 160.103. For the convenience of the parties, a "business associate" is a person or entity, other than a member of the workforce of covered entity, who performs functions or activities on behalf of, or provides certain services to, a covered entity that involve access by the business associate to Protected Health Information. A "business associate" also is a subcontractor that creates, receives, maintains, or transmits Protected Health Information on behalf of another business associate. And in reference to the party to this Business Associate Agreement "Business Associate" shall mean Contractor.
- 1.3 "Covered Entity" has the same meaning as the term "covered entity" at 45 C.F.R. § 160.103, and in reference to the party to this Business Associate Agreement, "Covered Entity" shall mean County.

- 1.4 "Data Aggregation" has the same meaning as the term "data aggregation" at 45 C.F.R. § 164.501.
- 1.5 "De-identification" refers to the de-identification standard at 45 C.F.R. § 164.514.
- 1.6 "Designated Record Set" has the same meaning as the term "designated record set" at 45 C.F.R. § 164.501.
- 1.7 "Disclose" and "Disclosure" mean, with respect to Protected Health Information, the release, transfer, provision of access to, or divulging in any other manner of Protected Health Information outside Business Associate's internal operations or to other than its workforce. (See 45 C.F.R. § 160.103.)
- 1.8 "Electronic Health Record" means an electronic record of health-related information on an individual that is created, gathered, managed, and consulted by authorized health care clinicians and staff. (See 42 U.S. C. § 17921.)
- 1.9 "Electronic Media" has the same meaning as the term "electronic media" at 45 C.F.R. § 160.103. For the convenience of the parties, electronic media means (1) Electronic storage material on which data is or may be recorded electronically, including, for example, devices in computers (hard drives) and any removable/transportable digital memory medium, such as magnetic tape or disk, optical disk, or digital memory card; (2) Transmission media used to exchange information already in electronic storage media. Transmission media include, for example, the Internet, extranet or intranet, leased lines, dial-up lines, private networks, and the physical movement of removable/transportable electronic storage media. Certain transmissions, including of paper, via facsimile, and of voice, via telephone, are not considered to be transmissions via electronic media if the information being exchanged did not exist in electronic form immediately before the transmission.
- 1.10 "Electronic Protected Health Information" has the same meaning as the term "electronic protected health information" at 45 C.F.R. § 160.103, limited to Protected Health Information created or received by Business Associate from or on behalf of Covered Entity. For the convenience of the parties, Electronic Protected Health Information means Protected Health Information that is (i) transmitted by electronic media; (ii) maintained in electronic media.
- 1.11 "Health Care Operations" has the same meaning as the term "health care operations" at 45 C.F.R. § 164.501.
- 1.12 "Individual" has the same meaning as the term "individual" at 45 C.F.R. § 160.103. For the convenience of the parties, Individual means the person who is the subject of Protected Health Information and shall include a person who qualifies as a personal representative in accordance with 45 C.F.R. § 164.502 (g).

- 1.13 "Law Enforcement Official" has the same meaning as the term "law enforcement official" at 45 C.F.R. § 164.103.
- 1.14 "Minimum Necessary" refers to the minimum necessary standard at 45 C.F.R. § 162.502 (b).
- 1.15 "Protected Health Information" has the same meaning as the term "protected health information" at 45 C.F.R. § 160.103, limited to the information created or received by Business Associate from or on behalf of Covered Entity. For the convenience of the parties, Protected Health Information includes information that (i) relates to the past, present or future physical or mental health or condition of an Individual; the provision of health care to an Individual, or the past, present or future payment for the provision of health care to an Individual; (ii) identifies the Individual (or for which there is a reasonable basis for believing that the information can be used to identify the Individual); and (iii) is created, received, maintained, or transmitted by Business Associate from or on behalf of Covered Entity, and includes Protected Health Information that is made accessible to Business Associate by Covered Entity. "Protected Health Information" includes Electronic Protected Health Information.
- 1.16 "Required by Law" " has the same meaning as the term "required by law" at 45 C.F.R. § 164.103.
- 1.17 "Secretary" has the same meaning as the term "secretary" at 45 C.F.R. § 160.103
- 1.18 "Security Incident" has the same meaning as the term "security incident" at 45 C.F.R. § 164.304.
- 1.19 "Services" means, unless otherwise specified, those functions, activities, or services in the applicable underlying Agreement, Contract, Master Agreement, Work Order, or Purchase Order or other service arrangement, with or without payment, that gives rise to Contractor's status as a Business Associate.
- 1.20 "Subcontractor" has the same meaning as the term "subcontractor" at 45 C.F.R. § 160.103.
- 1.21 "Unsecured Protected Health Information" has the same meaning as the term "unsecured protected health information" at 45 C.F.R. § 164.402.
- 1.22 "Use" or "Uses" means, with respect to Protected Health Information, the sharing, employment, application, utilization, examination or analysis of such Information within Business Associate's internal operations. (See 45 C.F.R § 164.103.)
- 1.23 Terms used, but not otherwise defined in this Business Associate Agreement, have the same meaning as those terms in the HIPAA Rules.

2. PERMITTED AND REQUIRED USES AND DISCLOSURES OF PROTECTED HEALTH INFORMATION

- 2.1 Business Associate may only Use and/or Disclose Protected Health Information as necessary to perform Services, and/or as necessary to comply with the obligations of this Business Associate Agreement.
- 2.2 Business Associate may Use Protected Health Information for de-identification of the information if de-identification of the information is required to provide Services.
- 2.3 Business Associate may Use or Disclose Protected Health Information as Required by Law.
- 2.4 Business Associate shall make Uses and Disclosures and requests for Protected Health Information consistent with the Covered Entity's applicable Minimum Necessary policies and procedures.
- 2.5 Business Associate may Use Protected Health Information as necessary for the proper management and administration of its business or to carry out its legal responsibilities.
- 2.6 Business Associate may Disclose Protected Health Information as necessary for the proper management and administration of its business or to carry out its legal responsibilities, provided the Disclosure is Required by Law or Business Associate obtains reasonable assurances from the person to whom the Protected Health Information is disclosed (i.e., the recipient) that it will be held confidentially and Used or further Disclosed only as Required by Law or for the purposes for which it was disclosed to the recipient and the recipient notifies Business Associate of any instances of which it is aware in which the confidentiality of the Protected Health Information has been breached.
- 2.7 Business Associate may provide Data Aggregation services relating to Covered Entity's Health Care Operations if such Data Aggregation services are necessary in order to provide Services.

3. PROHIBITED USES AND DISCLOSURES OF PROTECTED HEALTH INFORMATION

- 3.1 Business Associate shall not Use or Disclose Protected Health Information other than as permitted or required by this Business Associate Agreement or as Required by Law.
- 3.2 Business Associate shall not Use or Disclose Protected Health Information in a manner that would violate Subpart E of 45 C.F.R. Part 164 if done by Covered Entity, except for the specific Uses and Disclosures set forth in Sections 2.5 and 2.6.
- 3.3 Business Associate shall not Use or Disclose Protected Health Information for de-identification of the information except as set forth in section 2.2.

4. OBLIGATIONS TO SAFEGUARD PROTECTED HEALTH INFORMATION

- 4.1 Business Associate shall implement, use, and maintain appropriate safeguards to prevent the Use or Disclosure of Protected Health Information other than as provided for by this Business Associate Agreement.
- 4.2 Business Associate shall comply with Subpart C of 45 C.F.R Part 164 with respect to Electronic Protected Health Information, to prevent the Use or Disclosure of such information other than as provided for by this Business Associate Agreement.

5. REPORTING NON-PERMITTED USES OR DISCLOSURES, SECURITY INCIDENTS, AND BREACHES OF UNSECURED PROTECTED HEALTH INFORMATION

- 5.1 Business Associate shall report to Covered Entity any Use or Disclosure of Protected Health Information not permitted by this Business Associate Agreement, any Security Incident, and/ or any Breach of Unsecured Protected Health Information as further described in Sections 5.1.1, 5.1.2, and 5.1.3.
 - 5.1.1 Business Associate shall report to Covered Entity any Use or Disclosure of Protected Health Information by Business Associate, its employees, representatives, agents or Subcontractors not provided for by this Agreement of which Business Associate becomes aware.
 - 5.1.2 Business Associate shall report to Covered Entity any Security Incident of which Business Associate becomes aware.
 - 5.1.3 Business Associate shall report to Covered Entity any Breach by Business Associate, its employees, representatives, agents, workforce members, or Subcontractors of Unsecured Protected Health Information that is known to Business Associate or, by exercising reasonable diligence, would have been known to Business Associate. Business Associate shall be deemed to have knowledge of a Breach of Unsecured Protected Health Information if the Breach is known, or by exercising reasonable diligence would have been known, to any person, other than the person committing the Breach, who is an employee, officer, or other agent of Business Associate, including a Subcontractor, as determined in accordance with the federal common law of agency.
- 5.2 Except as provided in Section 5.3, for any reporting required by Section 5.1, Business Associate shall provide, to the extent available, all information required by, and within the times frames specified in, Sections 5.2.1 and 5.2.2.
 - 5.2.1 Business Associate shall make an immediate telephonic report upon discovery of the non-permitted Use or Disclosure of Protected Health Information, Security Incident or Breach of Unsecured Protected Health Information to **(562) 940-3335** that minimally includes:
 - (a) A brief description of what happened, including the date of the non-permitted Use or Disclosure, Security Incident, or Breach and the date of

Discovery of the non-permitted Use or Disclosure, Security Incident, or Breach, if known;

- (b) The number of Individuals whose Protected Health Information is involved;
- (c) A description of the specific type of Protected Health Information involved in the non-permitted Use or Disclosure, Security Incident, or Breach (such as whether full name, social security number, date of birth, home address, account number, diagnosis, disability code or other types of information were involved);
- (d) The name and contact information for a person highly knowledgeable of the facts and circumstances of the non-permitted Use or Disclosure of PHI, Security Incident, or Breach

5.2.2 Business Associate shall make a written report without unreasonable delay and in no event later than three (3) business days from the date of discovery by Business Associate of the non-permitted Use or Disclosure of Protected Health Information, Security Incident, or Breach of Unsecured Protected Health Information and to the **Chief HIPAA Privacy Officer at: Chief HIPAA Privacy Officer, Kenneth Hahn Hall of Administration, 500 West Temple Street, Suite 525, Los Angeles, California 90012, HIPAA@auditor.lacounty.gov**, that includes, to the extent possible:

- (a) A brief description of what happened, including the date of the non-permitted Use or Disclosure, Security Incident, or Breach and the date of Discovery of the non-permitted Use or Disclosure, Security Incident, or Breach, if known;
- (b) The number of Individuals whose Protected Health Information is involved;
- (c) A description of the specific type of Protected Health Information involved in the non-permitted Use or Disclosure, Security Incident, or Breach (such as whether full name, social security number, date of birth, home address, account number, diagnosis, disability code or other types of information were involved);
- (d) The identification of each Individual whose Unsecured Protected Health Information has been, or is reasonably believed by Business Associate to have been, accessed, acquired, Used, or Disclosed;
- (e) Any other information necessary to conduct an assessment of whether notification to the Individual(s) under 45 C.F.R. § 164.404 is required;
- (f) Any steps Business Associate believes that the Individual(s) could take to protect him or herself from potential harm from the non-permitted Use or Disclosure, Security Incident, or Breach;

- (g) A brief description of what Business Associate is doing to investigate, to mitigate harm to the Individual(s), and to protect against any further similar occurrences; and
 - (h) The name and contact information for a person highly knowledgeable of the facts and circumstances of the non-permitted Use or Disclosure of PHI, Security Incident, or Breach.
- 5.2.3 If Business Associate is not able to provide the information specified in Section 5.2.1 or 5.2.2 at the time of the required report, Business Associate shall provide such information promptly thereafter as such information becomes available.
- 5.3 Business Associate may delay the notification required by Section 5.1.3, if a law enforcement official states to Business Associate that notification would impede a criminal investigation or cause damage to national security.
- 5.3.1 If the law enforcement official's statement is in writing and specifies the time for which a delay is required, Business Associate shall delay its reporting and/or notification obligation(s) for the time period specified by the official.
- 5.3.2 If the statement is made orally, Business Associate shall document the statement, including the identity of the official making the statement, and delay its reporting and/or notification obligation(s) temporarily and no longer than 30 days from the date of the oral statement, unless a written statement as described in Section 5.3.1 is submitted during that time.

6. WRITTEN ASSURANCES OF SUBCONTRACTORS

- 6.1 In accordance with 45 C.F.R. § 164.502 (e)(1)(ii) and § 164.308 (b)(2), if applicable, Business Associate shall ensure that any Subcontractor that creates, receives, maintains, or transmits Protected Health Information on behalf of Business Associate is made aware of its status as a Business Associate with respect to such information and that Subcontractor agrees in writing to the same restrictions, conditions, and requirements that apply to Business Associate with respect to such information.
- 6.2 Business Associate shall take reasonable steps to cure any material breach or violation by Subcontractor of the agreement required by Section 6.1.
- 6.3 If the steps required by Section 6.2 do not cure the breach or end the violation, Contractor shall terminate, if feasible, any arrangement with Subcontractor by which Subcontractor creates, receives, maintains, or transmits Protected Health Information on behalf of Business Associate.
- 6.4 If neither cure nor termination as set forth in Sections 6.2 and 6.3 is feasible, Business Associate shall immediately notify County.
- 6.5 Without limiting the requirements of Section 6.1, the agreement required by Section 6.1 (Subcontractor Business Associate Agreement) shall require

Subcontractor to contemporaneously notify Covered Entity in the event of a Breach of Unsecured Protected Health Information.

- 6.6 Without limiting the requirements of Section 6.1, agreement required by Section 6.1 (Subcontractor Business Associate Agreement) shall include a provision requiring Subcontractor to destroy, or in the alternative to return to Business Associate, any Protected Health Information created, received, maintained, or transmitted by Subcontractor on behalf of Business Associate so as to enable Business Associate to comply with the provisions of Section 18.4.
- 6.7 Business Associate shall provide to Covered Entity, at Covered Entity's request, a copy of any and all Subcontractor Business Associate Agreements required by Section 6.1.
- 6.8 Sections 6.1 and 6.7 are not intended by the parties to limit in any way the scope of Business Associate's obligations related to Subcontracts or Subcontracting in the applicable underlying Agreement, Contract, Master Agreement, Work Order, Purchase Order, or other services arrangement, with or without payment, that gives rise to Contractor's status as a Business Associate.

7. ACCESS TO PROTECTED HEALTH INFORMATION

- 7.1 To the extent Covered Entity determines that Protected Health Information is maintained by Business Associate or its agents or Subcontractors in a Designated Record Set, Business Associate shall, within two (2) business days after receipt of a request from Covered Entity, make the Protected Health Information specified by Covered Entity available to the Individual(s) identified by Covered Entity as being entitled to access and shall provide such Individuals(s) or other person(s) designated by Covered Entity with a copy the specified Protected Health Information, in order for Covered Entity to meet the requirements of 45 C.F.R. § 164.524.
- 7.2 If any Individual requests access to Protected Health Information directly from Business Associate or its agents or Subcontractors, Business Associate shall notify Covered Entity in writing within two (2) days of the receipt of the request. Whether access shall be provided or denied shall be determined by Covered Entity.
- 7.3 To the extent that Business Associate maintains Protected Health Information that is subject to access as set forth above in one or more Designated Record Sets electronically and if the Individual requests an electronic copy of such information, Business Associate shall provide the Individual with access to the Protected Health Information in the electronic form and format requested by the Individual, if it is readily producible in such form and format; or, if not, in a readable electronic form and format as agreed to by Covered Entity and the Individual.

8. AMENDMENT OF PROTECTED HEALTH INFORMATION

- 8.1 To the extent Covered Entity determines that any Protected Health Information is maintained by Business Associate or its agents or Subcontractors in a Designated Record Set, Business Associate shall, within ten (10) business days after receipt of a written request from Covered Entity, make any amendments to such Protected Health Information that are requested by Covered Entity, in order for Covered Entity to meet the requirements of 45 C.F.R. § 164.526.
- 8.2 If any Individual requests an amendment to Protected Health Information directly from Business Associate or its agents or Subcontractors, Business Associate shall notify Covered Entity in writing within five (5) days of the receipt of the request. Whether an amendment shall be granted or denied shall be determined by Covered Entity.

9. ACCOUNTING OF DISCLOSURES OF PROTECTED HEALTH INFORMATION

- 9.1 Business Associate shall maintain an accounting of each Disclosure of Protected Health Information made by Business Associate or its employees, agents, representatives or Subcontractors, as is determined by Covered Entity to be necessary in order to permit Covered Entity to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 C.F.R. § 164.528.
- 9.1.1 Any accounting of disclosures provided by Business Associate under Section 9.1 shall include:
- (a) The date of the Disclosure;
 - (b) The name, and address if known, of the entity or person who received the Protected Health Information;
 - (c) A brief description of the Protected Health Information Disclosed; and
 - (d) A brief statement of the purpose of the Disclosure.
- 9.1.2 For each Disclosure that could require an accounting under Section 9.1, Business Associate shall document the information specified in Section 9.1.1, and shall maintain the information for six (6) years from the date of the Disclosure.
- 9.2 Business Associate shall provide to Covered Entity, within ten (10) business days after receipt of a written request from Covered Entity, information collected in accordance with Section 9.1.1 to permit Covered Entity to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 C.F.R. § 164.528
- 9.3 If any Individual requests an accounting of disclosures directly from Business Associate or its agents or Subcontractors, Business Associate shall notify Covered Entity in writing within five (5) days of the receipt of the request, and shall provide the requested accounting of disclosures to the Individual(s) within

30 days. The information provided in the accounting shall be in accordance with 45 C.F.R. § 164.528.

10. COMPLIANCE WITH APPLICABLE HIPAA RULES

10.1 To the extent Business Associate is to carry out one or more of Covered Entity's obligation(s) under Subpart E of 45 C.F.R. Part 164, Business Associate shall comply with the requirements of Subpart E that apply to Covered Entity's performance of such obligation(s).

10.2 Business Associate shall comply with all HIPAA Rules applicable to Business Associate in the performance of Services.

11. AVAILABILITY OF RECORDS

11.1 Business Associate shall make its internal practices, books, and records relating to the Use and Disclosure of Protected Health Information received from, or created or received by Business Associate on behalf of Covered Entity available to the Secretary for purposes of determining Covered Entity's compliance with the Privacy and Security Regulations.

11.2 Unless prohibited by the Secretary, Business Associate shall immediately notify Covered Entity of any requests made by the Secretary and provide Covered Entity with copies of any documents produced in response to such request.

12. MITIGATION OF HARMFUL EFFECTS

12.1 Business Associate shall mitigate, to the extent practicable, any harmful effect of a Use or Disclosure of Protected Health Information by Business Associate in violation of the requirements of this Business Associate Agreement that is known to Business Associate.

13. BREACH NOTIFICATION TO INDIVIDUALS

13.1 Business Associate shall, to the extent Covered Entity determines that there has been a Breach of Unsecured Protected Health Information by Business Associate, its employees, representatives, agents or Subcontractors, provide breach notification to the Individual in a manner that permits Covered Entity to comply with its obligations under 45 C.F.R. § 164.404.

13.1.1 Business Associate shall notify, subject to the review and approval of Covered Entity, each Individual whose Unsecured Protected Health Information has been, or is reasonably believed to have been, accessed, acquired, Used, or Disclosed as a result of any such Breach.

13.1.2 The notification provided by Business Associate shall be written in plain language, shall be subject to review and approval by Covered Entity, and shall include, to the extent possible:

- (a) A brief description of what happened, including the date of the Breach and the date of the Discovery of the Breach, if known;
 - (b) A description of the types of Unsecured Protected Health Information that were involved in the Breach (such as whether full name, social security number, date of birth, home address, account number, diagnosis, disability code, or other types of information were involved);
 - (c) Any steps the Individual should take to protect him or herself from potential harm resulting from the Breach;
 - (d) A brief description of what Business Associate is doing to investigate the Breach, to mitigate harm to Individual(s), and to protect against any further Breaches; and
 - (e) Contact procedures for Individual(s) to ask questions or learn additional information, which shall include a toll-free telephone number, an e-mail address, Web site, or postal address.
- 13.2 Covered Entity, in its sole discretion, may elect to provide the notification required by Section 13.1 and/or to establish the contact procedures described in Section 13.1.2.
- 13.3 Business Associate shall reimburse Covered Entity any and all costs incurred by Covered Entity, in complying with Subpart D of 45 C.F.R. Part 164, including but not limited to costs of notification, internet posting, or media publication, as a result of Business Associate's Breach of Unsecured Protected Health Information; Covered Entity shall not be responsible for any costs incurred by Business Associate in providing the notification required by 13.1 or in establishing the contact procedures required by Section 13.1.2.

14. INDEMNIFICATION

- 14.1 Business Associate shall indemnify, defend, and hold harmless Covered Entity, its Special Districts, elected and appointed officers, employees, and agents from and against any and all liability, including but not limited to demands, claims, actions, fees, costs, expenses (including attorney and expert witness fees), and penalties and/or fines (including regulatory penalties and/or fines), arising from or connected with Business Associate's acts and/or omissions arising from and/or relating to this Business Associate Agreement, including, but not limited to, compliance and/or enforcement actions and/or activities, whether formal or informal, by the Secretary or by the Attorney General of the State of California.
- 14.2 Section 14.1 is not intended by the parties to limit in any way the scope of Business Associate's obligations related to Insurance and/or Indemnification in the applicable underlying Agreement, Contract, Master Agreement, Work Order, Purchase Order, or other services arrangement, with or without payment, that gives rise to Contractor's status as a Business Associate.

15. OBLIGATIONS OF COVERED ENTITY

- 15.1 Covered Entity shall notify Business Associate of any current or future restrictions or limitations on the Use or Disclosure of Protected Health Information that would affect Business Associate's performance of the Services, and Business Associate shall thereafter restrict or limit its own Uses and Disclosures accordingly.
- 15.2 Covered Entity shall not request Business Associate to Use or Disclose Protected Health Information in any manner that would not be permissible under Subpart E of 45 C.F.R. Part 164 if done by Covered Entity, except to the extent that Business Associate may Use or Disclose Protected Health Information as provided in Sections 2.3, 2.5, and 2.6.

16. TERM

- 16.1 Unless sooner terminated as set forth in Section 17, the term of this Business Associate Agreement shall be the same as the term of the applicable underlying Agreement, Contract, Master Agreement, Work Order, Purchase Order, or other service arrangement, with or without payment, that gives rise to Contractor's status as a Business Associate.
- 16.2 Notwithstanding Section 16.1, Business Associate's obligations under Sections 11, 14, and 18 shall survive the termination or expiration of this Business Associate Agreement.

17. TERMINATION FOR CAUSE

- 17.1 In addition to and notwithstanding the termination provisions set forth in the applicable underlying Agreement, Contract, Master Agreement, Work Order, Purchase Order, or other services arrangement, with or without payment, that gives rise to Contractor's status as a Business Associate, if either party determines that the other party has violated a material term of this Business Associate Agreement, and the breaching party has not cured the breach or ended the violation within the time specified by the non-breaching party, which shall be reasonable given the nature of the breach and/or violation, the non-breaching party may terminate this Business Associate Agreement.
- 17.2 In addition to and notwithstanding the termination provisions set forth in the applicable underlying Agreement, Contract, Master Agreement, Work Order, Purchase Order, or other services arrangement, with or without payment, that gives rise to Contractor's status as a Business Associate, if either party determines that the other party has violated a material term of this Business Associate Agreement, and cure is not feasible, the non-breaching party may terminate this Business Associate Agreement immediately.

18. DISPOSITION OF PROTECTED HEALTH INFORMATION UPON TERMINATION OR EXPIRATION

- 18.1 Except as provided in Section 18.3, upon termination for any reason or expiration of this Business Associate Agreement, Business Associate shall return or, if agreed to by Covered entity, shall destroy as provided for in Section 18.2, all Protected Health Information received from Covered Entity, or created, maintained, or received by Business Associate on behalf of Covered Entity, that Business Associate, including any Subcontractor, still maintains in any form. Business Associate shall retain no copies of the Protected Health Information.
- 18.2 Destruction for purposes of Section 18.2 and Section 6.6 shall mean that media on which the Protected Health Information is stored or recorded has been destroyed and/or electronic media have been cleared, purged, or destroyed in accordance with the use of a technology or methodology specified by the Secretary in guidance for rendering Protected Health Information unusable, unreadable, or indecipherable to unauthorized individuals.
- 18.3 Notwithstanding Section 18.1, in the event that return or destruction of Protected Health Information is not feasible or Business Associate determines that any such Protected Health Information is necessary for Business Associate to continue its proper management and administration or to carry out its legal responsibilities, Business Associate may retain that Protected Health Information for which destruction or return is infeasible or that Protected Health Information which is necessary for Business Associate to continue its proper management and administration or to carry out its legal responsibilities and shall return or destroy all other Protected Health Information.
- 18.3.1 Business Associate shall extend the protections of this Business Associate Agreement to such Protected Health Information, including continuing to use appropriate safeguards and continuing to comply with Subpart C of 45 C.F.R Part 164 with respect to Electronic Protected Health Information, to prevent the Use or Disclosure of such information other than as provided for in Sections 2.5 and 2.6 for so long as such Protected Health Information is retained, and Business Associate shall not Use or Disclose such Protected Health Information other than for the purposes for which such Protected Health Information was retained.
- 18.3.2 Business Associate shall return or, if agreed to by Covered entity, destroy the Protected Health Information retained by Business Associate when it is no longer needed by Business Associate for Business Associate's proper management and administration or to carry out its legal responsibilities.
- 18.4 Business Associate shall ensure that all Protected Health Information created, maintained, or received by Subcontractors is returned or, if agreed to by Covered entity, destroyed as provided for in Section 18.2.

19. AUDIT, INSPECTION, AND EXAMINATION

- 19.1 Covered Entity reserves the right to conduct a reasonable inspection of the facilities, systems, information systems, books, records, agreements, and policies and procedures relating to the Use or Disclosure of Protected Health

Information for the purpose determining whether Business Associate is in compliance with the terms of this Business Associate Agreement and any non-compliance may be a basis for termination of this Business Associate Agreement and the applicable underlying Agreement, Contract, Master Agreement, Work Order, Purchase Order or other services arrangement, with or without payment, that gives rise to Contractor's status as a Business Associate, as provided for in section 17.

- 19.2 Covered Entity and Business Associate shall mutually agree in advance upon the scope, timing, and location of any such inspection.
- 19.3 At Business Associate's request, and to the extent permitted by law, Covered Entity shall execute a nondisclosure agreement, upon terms and conditions mutually agreed to by the parties.
- 19.4 That Covered Entity inspects, fails to inspect, or has the right to inspect as provided for in Section 19.1 does not relieve Business Associate of its responsibility to comply with this Business Associate Agreement and/or the HIPAA Rules or impose on Covered Entity any responsibility for Business Associate's compliance with any applicable HIPAA Rules.
- 19.5 Covered Entity's failure to detect, its detection but failure to notify Business Associate, or its detection but failure to require remediation by Business Associate of an unsatisfactory practice by Business Associate, shall not constitute acceptance of such practice or a waiver of Covered Entity's enforcement rights under this Business Associate Agreement or the applicable underlying Agreement, Contract, Master Agreement, Work Order, Purchase Order or other services arrangement, with or without payment, that gives rise to Contractor's status as a Business Associate.
- 19.6 Section 19.1 is not intended by the parties to limit in any way the scope of Business Associate's obligations related to Inspection and/or Audit and/or similar review in the applicable underlying Agreement, Contract, Master Agreement, Work Order, Purchase Order, or other services arrangement, with or without payment, that gives rise to Contractor's status as a Business Associate.

20. MISCELLANEOUS PROVISIONS

- 20.1 Disclaimer. Covered Entity makes no warranty or representation that compliance by Business Associate with the terms and conditions of this Business Associate Agreement will be adequate or satisfactory to meet the business needs or legal obligations of Business Associate.
- 20.2 HIPAA Requirements. The Parties agree that the provisions under HIPAA Rules that are required by law to be incorporated into this Amendment are hereby incorporated into this Agreement.

- 20.3 No Third Party Beneficiaries. Nothing in this Business Associate Agreement shall confer upon any person other than the parties and their respective successors or assigns, any rights, remedies, obligations, or liabilities whatsoever.
- 20.4 Construction. In the event that a provision of this Business Associate Agreement is contrary to a provision of the applicable underlying Agreement, Contract, Master Agreement, Work Order, Purchase Order, or other services arrangement, with or without payment, that gives rise to Contractor's status as a Business Associate, the provision of this Business Associate Agreement shall control. Otherwise, this Business Associate Agreement shall be construed under, and in accordance with, the terms of the applicable underlying Agreement, Contract, Master Agreement, Work Order, Purchase Order or other services arrangement, with or without payment, that gives rise to Contractor's status as a Business Associate.
- 20.5 Regulatory References. A reference in this Business Associate Agreement to a section in the HIPAA Rules means the section as in effect or as amended.
- 20.6 Interpretation. Any ambiguity in this Business Associate Agreement shall be resolved in favor of a meaning that permits the parties to comply with the HIPAA Rules.
- 20.7 Amendment. The parties agree to take such action as is necessary to amend this Business Associate Agreement from time to time as is necessary for Covered Entity or Business Associate to comply with the requirements of the HIPAA Rules and any other privacy laws governing Protected Health Information.